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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,809	04/13/2006	Avi Avramoff	560	5244

77345 7590 11/23/2009

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/575,809	AVRAMOFF ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *1 - 6, 8, 10 - 16, 18, 20, 21, 23 - 25, 51 - 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 - 32, 34, 36 - 42, 44, 46, 47, 49, 50, 58, 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/14/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1 - 6, 8, 10 - 16, 20, 21, 23 - 32, 34, 36 - 42, 44, 46, 47, 49 - 59.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 14, 2009 has been entered.

Applicants' arguments, filed September 14, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Objections

2. Claims 39 and 40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims depend from claim 27, which already requires the presence of the inorganic, alkaline

agent sodium stearate in the subcoating layer. Claims 39 and 40 require that the subcoating contain an organic basic salt (claim 39) such as sodium stearate (claim 40) but this ingredient has already been required by claim 27. Therefore, claims 39 and 40 do not further limit claim 27.

Claim Rejections - 35 USC § 112 – 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 12, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that lansoprazole is the only pharmaceutically active ingredient taught in the specification.

This argument is unpersuasive. While the claims have been amended from "sole active ingredient", to "sole pharmaceutically active ingredient", as pointed out in the

previous action, other agents present in formulations are pharmaceutically active even if they are not labeled as such by Applicant, such as lactose and sodium lauryl sulfate.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 26 – 32, 34, 36 – 40, 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (WO 96/24375) in view of Lundberg (EP 1174136) and Edgren et al. (US 6,210,712). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed March 12, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that there is no hint or suggestion in Edgren that any of the stearates disclosed as possible lubricants are suitable for use as an alkaline agent in a pharmaceutical composition, let alone a subcoating layer. The cited section of Edgren et al. refers to the inclusion of lubricants in the push-layer, not in the subcoating layer as taught by the present invention. None of the cited prior art documents teach the use of magnesium stearate in a subcoating layer. Applicant again maintains that magnesium stearate and sodium stearate are not functionally equivalent as alkaline agents. Magnesium stearate is not water soluble while sodium stearate is and Webster's defines an alkali as water-soluble compounds capable of turning litmus blue and reacting with an acid to form a salt and water.

These arguments are unpersuasive. The primary reference, Depui WO'375 teaches that a separating layer can be applied prior to the enteric coating that can optionally include an alkaline component such as a pH buffering compound (p 14, ln 28 – p 15, ln 1). Magnesium stearate is listed as an additive such as anti-tacking (lubricant)

agent that can be included in the composition (p 15, ln 12 – 15). Edgren discloses that magnesium, and other compounds, including sodium stearate, can act as lubricant. Edgren teaches that both magnesium stearate and sodium stearate both acts a lubricants in pharmaceutical compositions, so they are functionally equivalent for the role of the magnesium stearate taught by the primary reference, Depui WO'375 and thus it would be obvious to one of ordinary skill in the art to substitute one functionally equivalent, lubricant for another. Because sodium stearate and magnesium stearate are slightly different compounds, one of ordinary skill in the art would not expect these two compounds to have exactly the same properties. Applicants arguments about the different properties of the two stearate compounds would be germane if the stated purpose of the stearate ingredient in the cited prior art was to function as an alkaline agent, but that is not the stated purpose of the cited prior art. While the stated purpose for the presence of the active ingredient may be different between the cited prior art and the instant application (lubricant versus alkaline substance), the same composition results from the combination of Depui WO'375 in view of Lundberg and Edgren et al. as is recited in the instant claims.

The location for this ingredient is taught by the primary reference, which teaches a multi-layered oral dosage form wherein the drug is delivered by erosion of the outer layers to expose the active ingredient. Edgren et al. teaches an oral dosage form in which the delivery of the active agent is accomplished by a different mechanism – an osmotic drug delivery device (col 2, ln 11). The various functions an excipient can perform do not depend on the exact physical configuration of the dosage form, so one

of ordinary skill would not place the sodium stearate or magnesium stearate in a push layer as the PPI-delivering dosage forms of Depui WO'375 does not contain such a layer.

9. Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui WO'375, Lundberg and Edgren et al. further in view of Napper et al. (US 2002/0150618). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 12, 2009 and those set forth herein.

Applicant has not specifically addressed this rejection other than referring to Napper et al., so the rejection is maintained for the reasons set forth above with regard to Depui WO'375, Lundberg and Edgren et al. above.

10. Claims 26 – 32, 34, 36, 38 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (US 2002/0155153) in view of Lundberg (EP 1174136) and Edgren et al. (US 6,210,712). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 12, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Depui US'153 does not disclose a lansoprazole preparation in which an inorganic or organic basic salt is present in the separating layer. Lundberg does not disclose the use of magnesium stearate in the separating layer and does not disclose the use of magnesium stearate

as an alkaline agent. Edgren does not disclose that these stearates are functionally equivalent as alkaline agents but rather as lubricating agents as discussed above.

These arguments are unpersuasive. The Examiner is confused as to why Applicant states that Lundberg does not teach the inclusion of magnesium stearate in the intermediate layer between the enteric coating and the active ingredient containing layer as the example cited in the March 12, 2009 action clearly states (example 1, p 9, ln 41) that magnesium stearate is present. As mentioned on p 9 of the March 12, 2009 Office Action, the primary reference, Depui US'153 teaches the inclusion of inorganic salts, inorganic acids or organic bases such as basic amino acids or salts thereof in the separating layer to bolster the pH-buffering capacity of this layer (¶ [0062]).

As discussed in greater detail above, while the cited prior art may not identify sodium stearate as an alkaline agent to be included in the subcoating or separating layer, a composition with the same structure and ingredients as the instant claims is taught by the cited prior art, which renders the claims obvious.

11. Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui US'153, Lundberg and Edgren et al. further in view of Depui et al. (WO 96/24375) and Napper et al. (US 2002/0155153). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 12, 2009 and those set forth herein.

Applicant appears to address this rejection in the last two paragraphs of p 16 of the September 14, 2009 response as the teachings of Napper and WO'375 are briefly

mentioned but are introduced by a rejection statement that does not include these references. As none of the cited references disclose the use of a stearate as an alkaline agent in the subcoating layer, the use of lactose as a filler material would not result in the formulation of the present invention.

These arguments are unpersuasive. As discussed in greater detail above, the reason for inclusion of the stearate ingredient in the subcoating layer taught by the prior art does not need to the same as purpose identified by Applicant. A composition with the same structure and ingredients as the instant claims is taught by the cited prior art, which renders the claims obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW